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Proposed Class*

**UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA**

RICHARD DI DONATO, Individually and
On Behalf of All Others Similarly Situated,

Plaintiff,

v.

INSYS THERAPEUTICS, INC.; MICHAEL
L. BABICH; DARRYL S. BAKER; JOHN
N. KAPOOR; and ALEC BURLAKOFF,

Defendants.

No. 16-cv-00302-NVW

CLASS ACTION

**MEMORANDUM OF POINTS
AND AUTHORITIES IN
OPPOSITION TO MOTION TO
DISMISS**

**ORAL ARGUMENT
REQUESTED**

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I. INTRODUCTION

During the Class Period, Insys derived no less than 98% of its quarterly revenues from selling Subsys, a sublingual fentanyl spray that the FDA approved *only* for treating breakthrough cancer pain (“BTCP”) in adult patients already receiving around-the-clock opioid pain medication. Fentanyl is 50 times stronger than heroin, is at the center of this country’s ongoing opioid epidemic, and kills people every day. Because it is so dangerous, Subsys’ label warns that it can be fatal at any dose in persons who do not have BTCP, and Insys must comply with heightened regulations governing its promotion and sale of the drug. Subsys is also very expensive, and Defendants informed investors that Insys’ sales revenues from Subsys largely depended upon prescription coverage approval from third-party payers (“PBMs”).¹

Despite these challenges, Defendants reported that Subsys sales revenues—the single most important factor influencing Insys’ stock price—grew by more than 90% each quarter during the Class Period. Defendants’ public statements consistently attributed Insys’ impressive sales results to the facts that Subsys was a “clinically superior product,” for which there were “increased prescriptions” as a result of the Company’s “focused market penetration strategy” that “expanded the usage of Subsys *for BTCP*.” Defendants also claimed that Insys achieved its burgeoning Subsys sales from “proper” communications with PBMs, who helped patients afford their prescriptions. These were lies.

In truth, the Subsys sales revenues that Insys publicly reported during the Class Period were the byproduct of two interdependent components of a deliberate fraud that elevated Defendants’ profit motive over patient safety. *First*, Insys violated federal law

¹ Unless otherwise noted: (i) capitalized terms and abbreviations have the meanings ascribed to them in the Amended Complaint for Violation of the Federal Securities Laws (“AC”) (Doc. 49); (ii) all references to “¶” are to paragraphs in the AC; (iii) all references to “DB” are to Defendants’ Motion to Dismiss and Memorandum of Points and Authorities (Doc. 61); (iv) all references to “DX” are to exhibits to Defendants’ Request for Judicial Notice (Docs. 62-63); (v) all internal citations and quotation marks are omitted; and (vi) all emphasis is added.

1 by promoting Subsys for off-label use through a nationwide campaign that included: (i)
2 instructing the Company's sales force to avoid oncologists, and instead focus on doctors
3 who did not treat patients with BTCP; (ii) paying millions of dollars in illegal kickbacks
4 to doctors in exchange for high dose off-label Subsys prescriptions; and (iii) rewarding
5 its sales staff with outsized commissions for obtaining off-label Subsys prescriptions at
6 potentially lethal doses (the "Off-Label/Kickback Scheme"). *Second*, to "help" patients
7 pay for dangerous off-label Subsys prescriptions, Insys' IRC systematically defrauded
8 PBMs by, among other things, falsely claiming that patients had cancer and that doctors
9 wrote the high-dose scripts to treat BTCP (the "IRC Fraud").

10 The twin elements of Defendants' fraud to boost Subsys revenues were so
11 pervasive that more than 80% of Subsys prescriptions during the Class Period were for
12 off-label conditions, such as knee or back pain and headaches—none of which is
13 appropriately treated with a drug 50 times stronger than heroin. As the Class Period
14 proceeded, however, increased scrutiny gradually eroded the success of Defendants'
15 fraud, leading Insys to report at the end of the Class Period that it expected Subsys net
16 revenues for 1Q16 would be \$61 million to \$62 million—significantly lower than
17 consensus expectations of \$86 million for the same period. In response, Insys' stock
18 price declined by approximately 20% on April 11, 2016, and analysts concluded that
19 Insys "appeared to present a picture for Subsys that did not entirely square with reality."

20 Faced with the AC's well-pled allegations demonstrating their fraud, Defendants
21 premise their dismissal arguments upon the implausible notion that all Class Period
22 investors knew that Insys was an active criminal enterprise and that the AC, therefore,
23 contains only "recycled" facts and does not allege any "new news." Noticeably absent
24 from Defendants' factually and legally unsupported position is *any* reference to the IRC
25 Fraud, upon which Plaintiff's claims could stand alone. In any event, the AC adequately
26 alleges each element of all of Plaintiff's claims, and Defendants' motion should be
27 denied in its entirety.

1 *First*, the AC alleges with particularity each of Defendants’ false or misleading
2 statements addressing Insys’: (i) sources of sales revenues; (ii) interactions with PBMs;
3 and (iii) compliance with regulations. As set forth below in Section III.A, Defendants’
4 statements addressing each of these topics were false or misleading because Defendants
5 misrepresented and/or omitted material facts pertaining to the Off-Label/Kickback
6 Scheme and IRC Fraud, which were the cornerstones of Insys’ Class Period business.
7 Defendants cite no authority whatsoever for their broad contention that all of their
8 misstatements “were not misleading as a matter of law” (DB 12) based upon prior
9 allegations of misconduct, and Defendants’ sweeping request for dismissal on this basis
10 raises factual issues that cannot be resolved at this stage. Equally unavailing is
11 Defendants’ suggestion that Insys’ warning that it was potentially exposed to the risk of
12 employee misconduct insulates Defendants from their fraud. Such generic, boilerplate
13 risk disclosures provide no shelter here, where Defendants were engaged in an *ongoing*
14 *fraud* and none of Defendants’ misstatements was forward-looking.

15 *Second*, the AC adequately alleges that each Defendant acted with scienter when
16 making the alleged misstatements. In addition to pleading facts demonstrating
17 Defendants’ direct knowledge and access to information undermining their public
18 statements, the AC alleges the indisputable fact that Subsys accounted for 98% or more
19 of Insys’ Class Period revenues, rendering it absurd to suggest that Defendants did not
20 know or were not deliberately reckless in disregarding that the Off-Label/Kickback
21 Scheme and IRC Fraud gave rise to the increasing Subsys sales that Defendants
22 celebrated during the Class Period. *See Berson v. Applied Signal Tech., Inc.*, 527 F.3d
23 982, 988 n.5, 989 (9th Cir. 2008). Having challenged the AC’s falsity allegations on the
24 basis that all investors supposedly knew of the fraud, Defendants cannot credibly claim
25 that they, alone, were ignorant. In light of Defendants’ admission that Subsys was “so
26 important” to Insys that Defendants met “every single day” to discuss Subsys
27 prescriptions, Defendants simply fail to muster any inference of non-fraudulent intent
28

1 that is more cogent and compelling than the inference of scienter that the AC's
2 collective allegations raise. *See* §III.B, *infra*.

3 *Third*, the AC's loss causation allegations are sufficient, as they plainly provide
4 "some indication of the loss and the causal connection that that the plaintiff has in
5 mind." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005). For each of the nine
6 partial corrective disclosures and/or materializations of foreseeable risks that removed
7 portions of the artificial inflation in Insys' stock price, the AC: (i) identifies the new
8 information revealed that undermined Defendants' prior statements; (ii) connects this
9 new information to the Off-Label/Kickback Scheme and/or IRC Fraud; and (iii) alleges
10 the foreseeable negative impact that the new information had upon Insys' stock price.
11 Nothing more is required. *See* §III.C, *infra*. Defendants' contention that none of the nine
12 disclosures revealed new news is factually incorrect and belied by the AC's allegations
13 demonstrating the significant declines in Insys' stock price in response to each.
14 Defendants concede that Insys common stock traded in an efficient market during the
15 Class Period, and a company's stock price in such a market does not react to "old
16 news." Accordingly, Defendants' motion should be denied.

17 **II. STATEMENT OF FACTS**

18 **A. Insys and Subsys**

19 Insys is a pharmaceutical company, and its common stock trades on the
20 NASDAQ—an efficient securities market. ¶¶27, 347-52. The Company's only FDA-
21 approved product during the Class Period was Subsys, a sublingual fentanyl spray. ¶¶6-
22 8, 57-58. Fentanyl is an opioid pain medication that is 50 times stronger than heroin,
23 causes daily overdose deaths, and is at the center of the United States' opioid epidemic.
24 ¶¶3-5, 50-55. Approved by the FDA in January 2012, the *only* "on-label" use of Subsys
25 is to treat BTCP in opioid-tolerant adults, and it is contraindicated for "acute or
26 postoperative pain including headache/migraine." ¶¶7-8, 60-62. Subsys single-use
27 sprays are available in doses ranging from 100mcg to 1600mcg. ¶59.
28

Subsys is so dangerous that its “black box warning” label cautions that “[l]ife threatening respiratory depression and death could occur *at any dose* in opioid non-tolerant patients.” ¶¶7-8, 60-62. As a result, “[t]he initial dose of Subsys is always 100mcg,” unless the patient already has used fentanyl; then, it is never higher than 400mcg, and physicians should increase doses only where the current dose is ineffective. ¶60. Due to its serious risks, Subsys is subject to, and doctors who prescribe it must be enrolled in, the TIRF-REMS Access Program. ¶¶6, 10, 63-78.

Subsys also is extremely expensive, costing over \$21,000 per month for 240 doses of Subsys 1,200mcg (¶59), leading Defendants to acknowledge that “*sales of, and revenue from, Subsys depend in significant part on the coverage and reimbursement policies of third-party payers*” (¶¶9, 74, 184, 199, 217). PBMs require prior authorization of Subsys prescriptions. ¶137. Based on the PBMs’ formularies, appropriate authorizations are limited to on-label use. *Id.*

During the Class Period, *Subsys generated more than 98% of Insys’ revenues*, and was “so important” to Defendants that they met to discuss Subsys prescriptions “*every single day*.” ¶¶57, 79, 256, 269-70, 287. Stock analysts relied upon Subsys sales to gauge Insys’ performance, and the publicly reported sales revenue drove the price of Insys common stock. ¶¶182, 270.

B. Defendants’ Off-Label Marketing/Kickback Scheme and IRC Fraud

Insys launched Subsys into a mature market with a limited on-label indication and patient population in March 2012. ¶79. Despite these headwinds, Insys revenues from Subsys grew by more than 90% every quarter during the Class Period. *Id.* Defendants consistently attributed Subsys revenues and “increased prescriptions” to the “successful execution of [Insys’] Subsys strategy,” including a “focused market penetration strategy” that “expand[ed] the usage of Subsys for BTCP.” ¶¶80, 176-77, 187, 197-98, 207, 212. Unbeknownst to investors, however, Subsys’ revenues depended upon Insys’ Off-Label/Kickback Scheme and IRC Fraud.

1 1. Insys' Off-Label Marketing/Kickback Scheme

2 Despite reassuring investors that BTCP was “all we want to address with a
3 doctor” (¶¶193, 285), Defendants pursued the Off-Label/Kickback Scheme, which was
4 so pervasive that approximately 80% of Subsys prescriptions were written for off-label
5 use. ¶¶15, 94, 173. For example, Defendants instructed Insys’ sales force to promote
6 Subsys for off-label use by, among other things: (i) targeting doctors who had neither
7 cancer patients nor prior experience prescribing TIRFs; (ii) avoiding doctors who could
8 prescribe Subsys for BTCP because their “*patients would die soon . . . and couldn’t*
9 *titrate*” to a higher dose; and (iii) encouraging doctors to write higher than
10 recommended doses of Subsys. ¶¶84-93, 95-100. Defendants also urged the sales force
11 to review doctors’ files for Subsys candidates, irrespective of whether the prescription
12 would be on-label (¶106), and if a doctor prescribed a low initial dose, Insys’ sales
13 representatives received an automatic email, copying “top management,” and
14 instructing the sales representative to “report back to your manager within 24 hours . . .
15 on HOW the doctor plans to titrate the patient to an effective dose.” ¶104.

16 Defendants also financially motivated Insys’ sales force to promote Subsys off-
17 label, including paying a base salary 50% below the industry standard, which forced
18 employees to earn sales commissions to make a decent wage. ¶¶101-03. These
19 commissions were based on the number of prescriptions, and higher doses generated
20 higher payouts. *Id.* One sales representative, Perhaps, who pled guilty in February 2016
21 to paying kickbacks to two Alabama doctors for off-label Subsys prescriptions, received
22 \$700,000 in commissions from 2013 to 2015. ¶¶19, 37, 101-03, 143-44, 242, 246.

23 Likewise, Insys paid prescribers millions of dollars in illegal kickbacks for off-
24 label Subsys prescriptions. ¶¶109-20. Through its “speakers program,” for example,
25 Insys paid doctors up to \$2,400 for each “educational” event. ¶¶89, 114. In reality, these
26 events were a “front” for kickbacks, hosted by inexperienced “speakers,” who rarely
27 discussed Subsys, and were often attended by the speaker’s own staff, the Insys sales
28

1 representative who recruited the speaker, and/or prescribers who did not treat cancer
2 patients or were not qualified to prescribe TIRFs. ¶¶109-120. Defendants and program
3 participants understood that speaker fees were a *quid pro quo* (e.g., ¶123), with
4 Defendants constantly assessing Insys’ “return on investment” (¶¶122-23, 125-29), and
5 doctors acknowledging that their kickbacks were in exchange for prescribing Subsys at
6 high doses (¶¶122-23, 130). Defendants also provided prescribers with meals, drinks,
7 and other “entertainment” in exchange for off-label Subsys prescriptions. ¶¶131-35.

8 **2. The IRC Fraud**

9 Defendants’ Off-Label/Kickback Scheme would not have increased Subsys
10 revenues without the parallel IRC Fraud. ¶¶15, 136-64. Deliberately kept separate from
11 the rest of the Company, the IRC systematically defrauded PBMs to obtain coverage for
12 off-label Subsys prescriptions (*id.*), and IRC staff received bonuses for succeeding in
13 their fraud (¶¶19, 143-44). From its inception until December 2013, the IRC used a
14 script that required employees to lie to PBMs about a patient’s diagnosis, substituting
15 BTCP diagnoses for non-cancer pain, and falsely replying “yes” when PBMs asked
16 whether the patient had BTCP. ¶¶145-50. Insys subtly changed this “script” after the
17 DHHS issued a subpoena regarding Subsys in December 2013, and these changes
18 allowed Insys to maintain high rates of insurance coverage for off-label Subsys
19 prescriptions through the spring of 2014. ¶152.

20 By the start of the Class Period, however, Insys faced increasing scrutiny from
21 regulators and PBMs, leading to declining off-label Subsys authorizations. ¶¶153-54. In
22 response, Insys instituted “the spiel,” which directed IRC employees to respond to direct
23 questions about the patient’s diagnosis as follows: “The physician has stated that Subsys
24 is approved for treating breakthrough cancer pain so [he] is treating breakthrough pain.”
25 ¶¶154-55. Additionally, Insys instructed IRC staff to purposefully substitute cancer
26 pain-related codes for general pain codes. ¶156. These tactics stabilized approvals for
27 off-label Subsys prescriptions in the fall of 2014. *Id.*

1 However, Insys again experienced declining PBM approvals for Subsys in the
 2 spring of 2015 (¶¶158-59), which dropped to two dozen per week for the entire unit by
 3 early autumn 2015, as compared to 25 per employee per week in 2014 (¶160). In
 4 response, Insys developed “Statement 13,” which directed IRC staff to continue to use
 5 “the spiel,” but instructed them for the first time to state the correct insurance pain code
 6 if pressed by the PBM. ¶¶160-61. Statement 13, however, did not stabilize Subsys
 7 approvals, leading to brainstorming sessions to develop new tactics in November 2015.
 8 ¶162. One such session, a recording of which was made public in a January 25, 2016
 9 *SIRF* article, revealed Insys’ fraudulent means of obtaining authorizations for off-label
 10 Subsys prescriptions during the Class Period. ¶¶162-63. With the IRC Fraud
 11 foundering, Subsys prescriptions flattened, but the inevitable decline in Subsys revenues
 12 was temporarily stemmed by higher dose off-label Subsys prescriptions written to
 13 existing patients with approved insurance coverage for the drug. ¶164.

14 **C. The Misrepresented and Concealed Fraud is Gradually Revealed**

15 The relevant truth of Defendants’ misconduct began leaking out in November
 16 2014, when the *New York Times* highlighted the amount of kickbacks Insys paid to top-
 17 Subsys prescribers based on data from a new federal database. ¶¶304-05; DX21. New
 18 information regarding Defendants’ conduct continued to surface throughout the first
 19 half of 2015, culminating in the disclosure of the arrests of two top Subsys prescribers
 20 for improper prescriptions (¶312; DX23) and the guilty plea of Alfonso, a nurse who
 21 admitted to receiving \$83,000 in Insys kickbacks (¶¶316-19; DX24-26). Thereafter,
 22 several news articles published from November 2015 through January 2016 provided
 23 previously undisclosed details of Defendants’ misconduct based on first-hand accounts,
 24 documents, and recorded conversations. ¶¶238-45, 320-36. Kapoor terminated Babich
 25 in November 2015 because he was “closest to the issues” under investigation, as
 26 reflected by, among other things, his approval of the “budgeted payments” that Alfonso
 27 pled guilty to receiving. ¶¶240-42, 260, 283, 324-26, 328-30; DX31.

Despite the gradual emergence of previously misrepresented and concealed information partially revealing their misconduct and the risks concealed thereby, Defendants denied marketing Subsys off-label. *See, e.g.*, ¶¶193-94. Likewise, after announcing a settlement with the ODOJ related to Subsys (¶¶237-238), Defendants claimed that they were “committed to complying with laws governing [Subsys’] sales, marketing and promotional practices” (¶¶204, 206, 224). Additionally, in press releases dated November 23, 2015 and January 25, 2016 responding to the new details of their misconduct, Defendants lied about the primary driver of Subsys revenues (*e.g.*, citing “the clinical attributes of Subsys,” ¶224), and claimed that “the recent media reports’ account of the Company’s practices [were] unreliable”(¶228).

By 1Q16, Insys could no longer match the revenues earned through the Off-Label/Kickback Scheme and IRC Fraud. On April 11, 2016, Insys significantly lowered its expectations for 1Q16, reducing Subsys net revenues from \$86 million to \$61 million to \$62 million. ¶¶247-51, 337-38. Analysts were quick to report, among other things, that the decline in scripts was due to “price and payer coverage considerations,” with “fewer patients . . . initiating therapy (¶251), and that “*INSY appeared to present a picture for Subsys that did not entirely square with reality*” (¶249). In response to this news revealing that the Company’s Class Period revenues were propelled by a concealed fraud, the price of Insys common stock declined by 19.37%. ¶339.

III. ARGUMENT

In assessing a Rule 12(b)(6) motion, courts consider the complaint in its entirety, “accept all factual allegations . . . as true” and construe them in the light most favorable to plaintiff. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). A complaint should not be dismissed if it contains sufficient factual matter that, accepted as true, states a claim for relief that is plausible on its face. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).²

² Plaintiff does not object to the incorporation by reference or judicial notice of Defendants’ exhibits consistent with Fed. R. Evid. 201, which does not permit

A. The AC Pleads Actionable Misstatements

A complaint pleads falsity where it “specif[ies] each statement alleged to have been misleading” and “the reason or reasons why the statement is misleading.” 15 U.S.C. §78u-4(b)(1)(B). Such allegations must be particularized and are subject to Rule 9(b), which requires plaintiffs to plead “the time, place, and content” of the false representations as well as the identities of the parties to the misrepresentations. *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007). The relevant question is “whether the facts alleged are sufficient to support a reasonable belief” that the alleged misstatements were misleading. *In re CytRx Corp. Sec. Litig.*, 2015 WL 5031232, at *3 (C.D. Cal. July 13, 2015). As set forth below, Plaintiff satisfies these requirements.³

1. Defendants Misstated Insys’ Relationships with PBMs

The AC adequately alleges that Defendants repeatedly misled investors concerning Insys’ interactions with PBMs during the Class Period. ¶¶167- 68, 184, 199, 208, 217, 228. These relationships were critical—Subsys was expensive for consumers, leading Defendants to concede that “[o]ur sales of, and revenue from, Subsys, depend in significant part upon . . . third party payers.” ¶¶9, 74, 199, 208, 217. Defendants thus reassured investors that “[w]e continue to properly communicate with all the major plans and the PBMs to ensure proper access for Subsys” (¶168); and that the IRC “provides administrative support assistance to help patients work with their insurance companies” (¶¶184, 199, 208, 217).

Each of these statements was misleading because Defendants failed to disclose the IRC Fraud (¶¶173, 180, 192, 202, 210, 220), which involved deceiving PBMs into

inferences from these documents to be drawn in Defendants’ favor. *See United States ex rel. Lee v. Corinthian Colleges*, 655 F.3d 984, 999 (9th Cir. 2011).

³ Defendants argue for dismissal because the AC alleges statements were both “false **and** misleading.” DB 9-10, 12-13. But, a statement that is false also is misleading. *See, In re New Century*, 588 F. Supp. 2d 1206, 1225 (C.D. Cal. 2008) (“statements were false **and** misleading when made.”). Regardless, the AC, in fact, alleges that all of the challenged statements were “materially false and misleading when made **or** omitted material information such that they were rendered misleading.” *See, e.g.*, ¶¶172, 179, 189, 195, 201, 209, 219, 225, 229.

authorizing coverage for off-label Subsys prescriptions by, among other tactics: (i) deliberately falsifying patient diagnoses (¶¶145-46, 148, 150, 156, 163); and (ii) using Company-generated scripts to lie during telephone conversations with PBM personnel (¶¶145-46, 151, 155, 160-61, 163). *See also* ¶¶136-59, 255-71, 276-77, 285-90, 299-301. As a result of these efforts, more than 80% of Subsys prescriptions during the Class Period were for off-label uses that the PBMs would not have covered absent Defendants' lies. ¶¶15, 94, 173.

By concealing the IRC Fraud when discussing Insys' PBM interactions, Defendants "affirmatively create[d] an impression of a state of affairs that differ[ed] in a material way from the one that actually exist[ed]." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002); *see In re Apollo Grp., Inc. Sec. Litig.*, 395 F. Supp. 2d 906, 921 (D. Ariz. 2005) (falsity adequately pled where defendants "not only failed to disclose important negative facts in their possession, but actually painted a picture that was contrary to the facts they possessed"). In particular, statements that the IRC engaged in "proper" business practices to "help" patients obtain insurance coverage for Subsys materially "misled investors by implicitly and falsely warranting that there were no illegal practices contributing to [Insys'] success." *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1034 (C.D. Cal. 2008); *see also In re Syncor Int'l Corp. Sec. Litig.*, 239 F. App'x 318, 320 (9th Cir. 2007) ("By attributing Syncor's success solely to legitimate practices, defendants implicitly (and falsely) warranted that there were no illegal practices contributing to that success."). Insys' statements rejecting the facts revealing the IRC Fraud set forth in the January 25, 2016 *SIRF* article misled investors for the same reasons. ¶¶158-63, 227-29.

2. Defendants Misled Investors Concerning Subsys Sales

Defendants also misled investors when discussing the bases for the increasing Subsys sales—the source of almost 100% of Insys' revenues during the Class Period. For instance, Defendants attributed Subsys' sales growth to: (i) "successful execution of

our Subsys strategy” (e.g., ¶¶166, 175); (ii) Subsys’ “superior” “clinical attributes” (e.g., ¶¶167, 176, 182-83, 224); (iii) Insys’ “focused market penetration strategy” (e.g., ¶¶167, 176, 182); (iv) a “change in mix of prescribed dosages” (e.g., ¶¶169, 177, 198, 207, 215-16); and (v) “expanding the usage of Subsys for BTCP by building awareness among oncologists” regarding Subsys’ benefits (¶¶183, 187).

In truth, Insys’ growing Subsys revenues were due to the IRC Fraud (discussed above) and the Off-Label/Kickback Scheme (¶¶172, 179, 189-91, 201, 219, 225), which included: (i) instructing and incentivizing Insys’ sales force to promote off-label uses of Subsys to doctors who already wrote off-label fentanyl prescriptions, did not treat cancer patients, and/or were not qualified to prescribe Schedule II opioids (¶¶83-94; 101-03, 191); and (ii) paying millions of dollars in illegal kickbacks to doctors in exchange for high-dose off-label Subsys prescriptions (e.g., ¶¶109-35).⁴

Defendants’ omission of these facts from their statements addressing the putative reasons for Subsys’ sales success created the misimpression that such sales were “driven by strong demand, when in fact those sales were attributable in large part to illegal ‘off-label’ marketing of the drug.” *In re Gilead Scis. Sec. Litig.*, 2009 WL 1561584, at *1 (N.D. Cal. June 3, 2009); *see also Mauss v. NuVasive, Inc.*, 2015 WL 10857519, at *9 (S.D. Cal. Aug. 28, 2015) (allegations that “investors were led to believe that the [company’s] reported revenues and expenditures were attributable to legal activity, when that was not the case” were “sufficient”); *Neborsky v. Valley Forge Composite Techs., Inc.*, 2014 WL 3767011, at *6 (S.D. Cal. July 29, 2014) (false statements concerning revenues sustained where defendants “deliberately withheld complete information related to those revenues with the intent to conceal illegal conduct”).⁵

⁴ The AC does not allege that Insys improperly marketed to all fentanyl prescribers, as Defendants incorrectly contend. DB 10. Rather, the AC alleges that it was improper for Insys to target doctors who had *previously written off-label* fentanyl prescriptions for, among others, Cephalon, which paid \$425 million to settle civil and criminal charges related to improper off-label fentanyl marketing. ¶86.

⁵ *Accord Minneapolis Firefighters’ Relief Ass’n v. Medtronic, Inc.*, 2010 U.S. Dist. LEXIS 10029, *21-22 (D. Minn. Feb. 3, 2010) (statements attributing sales growth to increased on-label use and new FDA approvals actionable where growth “was due to

3. Defendants Misstated Insys' Compliance Measures

Defendants falsely denied the allegations related to regulatory and public scrutiny of the Off-Label/Kickback Scheme and the IRC Fraud, claiming that Insys: (i) was “committed to complying with laws governing its sales, marketing and promotional practices” (¶¶204, 206); (ii) maintained “controls regarding relationships with health care providers” (¶218); and (iii) had protocols “designed to ensure its sales and marketing practices comply with applicable laws” (¶224). When information emerged in the January 25, 2016 *SIRF* article partially revealing the IRC Fraud, Insys similarly claimed that IRC staff “undergo specific training on applicable laws and regulations” and that Insys “continues to strive to comply with applicable laws.” ¶228.

Statements regarding a company’s efforts “to achieve and maintain . . . compliance” are false where the complaint alleges material adverse facts demonstrating the company “was not equipped to address and remedy” its compliance-related deficiencies. *Mulligan v. Impax Labs., Inc.*, 36 F. Supp. 3d 942, 958-959 (N.D. Cal. 2014). Here, the AC alleges that Subsys revenues were still elevated by the Off-Label/Kickback Scheme and IRC Fraud when Defendants made these statements (from August 6, 2015 through January 25, 2016). ¶¶209, 222, 226. At this time, Insys’ IRC continued to devise and employ strategies to dupe PBMs into approving off-label Subsys prescriptions in the face of increasing resistance. ¶¶159-63, 209, 222, 226, 229. Accordingly, these statements are actionable under §10(b). *See Reese v. Malone*, 747 F.3d 557, 578 (9th Cir. 2014) (statement that company was “in compliance” with laws actionable where complaint alleged numerous violations); *Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 742 (9th Cir. 2008) (same); *Impax*, 36 F. Supp. 3d at 960 (statements about compliance with FDA regulations actionable where recurring violations “call into question whether there was ever a true commitment to remedy” off-label use”); *In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 368-69 (E.D.N.Y. 2013) (statements putting source of Medicare revenue at issue actionable where defendants failed to disclose that a portion was derived from Medicare fraud).

such issues); *accord Meyer v. JinkoSolar Hldgs. Co.*, 761 F.3d 245, 251 (2d Cir. 2014) (statement about compliance with environmental regulations actionable where measures failed to prevent violations).

4. Defendants' Challenges to Falsity Fail

Defendants' efforts to discredit the AC's falsity allegations are factually baseless and legally unsupported. *First*, relying on the "bespeaks caution" doctrine and the PSLRA safe-harbor for forward-looking statements, Defendants erroneously contend that many of their misstatements were forward-looking and therefore could not have been misleading in light of the vague "disclosure" that Insys is "exposed to the risk of employee misconduct." DB 12-14. As an initial matter, neither the bespeaks caution doctrine nor the PSLRA safe harbor insulates any of the statements at issue here because none was forward-looking. *See Livid Hldgs. Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 949 (9th Cir. 2005). In their *only* example, Defendants selectively quote Babich's March 3, 2015 statement (DB 15), but when "examined as a whole," this statement plainly addressed Insys' current putative marketing efforts: "[w]e *have* some very unique programs within the oncology setting that we *continue* to execute on[.]" ¶183; *see No. 84 Emp'r-Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 937 (9th Cir. 2003).⁶

However, even if the bespeaks caution doctrine or the PSLRA safe harbor applied (they do not), they are rarely, if ever, appropriate bases for a Rule 12(b)(6) dismissal because "there must be sufficient cautionary language or risk disclosure [such] that reasonable minds could not disagree that the challenged statements were not

⁶ Defendants purport to flag other allegedly forward-looking misstatements without explaining how the PSLRA safe harbor applies. DB 15 n.11. Nevertheless, the PSLRA safe harbor provides no insulation here because each statement misrepresented a present or historical fact, or omitted material information. *See* ¶¶166, 182, 197, 212 (reasons for *past* Subsys sales growth); ¶¶184, 199, 208, 217 (putative services that the IRC *presently* provides); ¶213 (statement of *present* fact, "[w]e only call on REMS doctors") ¶218 (explaining *past* putative remedial actions "we have taken").

misleading.” *Livid Hldgs.*, 416 F.3d at 947.⁷ Defendants fail to make the requisite “stringent showing.” *Id.* Instead, Defendants assert that a boilerplate warning of Insys’ potential exposure to employee misconduct allows them to sidestep the securities laws. Numerous courts have rejected similar arguments. *See, e.g., Meyer*, 761 F.3d at 251 (“generic warning of risk will not suffice when undisclosed facts on the ground would substantially affect a reasonable investor’s calculations of probability”); *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1035 (S.D. Cal. 2005) (warning that study results for drug may never become available was too generic “to present investors with any indications as to the likelihood of future . . . studies facing obstacles”); *In re Amylin Pharm., Inc. Sec. Litig.*, 2003 WL 21500525, at *7 (S.D. Cal. May 1, 2003).

Moreover, none of Defendants’ purported “risk” disclosures alerted the market to the specific facts that Plaintiff alleges were misrepresented and concealed. For example, Insys’ generalized warning that “[o]ur employees *may* engage in misconduct” said nothing to investors regarding the *ongoing* IRC Fraud or the *continued* involvement of the Company’s executives in the Off-Label/Kickback Scheme. *See, e.g., Berson*, 527 F.3d at 987 (representation that something “might” occur is “quite different” from statement that it has “in fact” occurred because “[o]ne indicates a risk, the other a certainty[,]” and “investors would treat the two differently”).⁸ Nor did Insys’ broad assertions that the IRC is “subject to extensive and complex federal and state laws” and

⁷ Tellingly, the case Defendants cite for their inherently fact-specific bespeaks caution defense, *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407 (9th Cir. 1994), was decided at the summary judgment stage. DB 11.

⁸ Burlakoff’s complicity in the Off-Label/Kickback Scheme renders baseless his argument that his statements in ¶194 were not false or misleading because he “was addressing Company policy, not the actions of certain employees.” DB 29. *See* ¶195 & *supra* at II.A.2. Burlakoff’s contention that the April 24, 2015 *SIRF* article purportedly “undermined” the falsity of these outright lies also should be swiftly rejected. *Id.* Burlakoff likewise incorrectly asserts that Plaintiff has failed to establish that investors relied on his statements in the April 24, 2015 *SIRF* article. DB 30. The AC, however, sufficiently alleges that Insys common stock traded in an efficient market (which Defendants do not challenge) and invokes the fraud-on-the-market presumption of reliance. ¶¶347-52. *See, e.g., Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2408 (2014) (in fraud-on-market case, “reliance on any public misrepresentations” is presumed).

1 “companies that violate such laws, regulations and standards may face substantial
 2 penalties” (DB 13), alert investors to the IRC’s *actual* violations of the laws. *See Flynn*
 3 *v. Sientra, Inc.*, 2016 WL 3360676, at *10 (C.D. Cal. June 9, 2016) (disclosure merely
 4 addressing risks of regulatory and legal non-compliance “in the abstract, with no
 5 indication that th[is] risk[] may already have come to fruition” insufficient). Finally,
 6 Defendants’ suggestion that Insys’ disclosure of “specific law enforcement
 7 investigations” somehow alerted investors to the conduct forming the basis of Plaintiff’s
 8 claims (DB 11), is belied by Defendants’ denials of those allegations and false
 9 assurances that Insys complied with applicable laws. *See, e.g.*, ¶¶218, 224, 228; *In re*
 10 *Cobalt Int’l Energy Inc. Securities Litig.*, 2016 WL 215476, *4-5 (S.D. Tex. Jan. 19,
 11 2016) (falsity of statements denying allegations of wrongdoing published in news
 12 articles adequately alleged).⁹

13 *Second*, Defendants’ contentions that their statements concerning Insys’
 14 revenues, PBM relationships, and compliance measures were not misleading also fail.
 15 DB 10-11. In support, Defendants principally rely upon *Metzler Investment GMBH v.*
 16 *Corinthian Colls., Inc.*, 540 F.3d 1049 (9th Cir. 2008). *Metzler* is factually inapposite,
 17 however, because the plaintiff there offered only the conclusory allegation that all of the
 18 company’s financial results *were overstated* as a result of a company-wide scheme to
 19 inflate student-enrollment figures. *See id.* at 1070-71. Here, Plaintiff does not allege that
 20 Insys’ financial *results* were false, as Defendants recognize. DB 10. Rather, Plaintiff
 21 challenges statements concerning the putative *sources* of Insys’ revenues. *See* ¶¶166,
 22 169, 175-77, 182-83, 186-87, 197-98, 207, 212-13, 215-16, 224.

23 Nor does Plaintiff rely upon a broad “allegation that general statements about the
 24 Company left the misimpression that its performance was due to ‘legitimate business

25 ⁹ Defendants’ contention that the reasons given for Babich’s “resignation” were
 26 not false because “the regulatory investigations were never concealed from investors”
 27 (DB 14 n.10), misses the mark. Instead, the putative reasons given for Babich’s
 28 “resignation” were misleading because Defendants concealed that Kapoor fired Babich
 due to his role in the misconduct being investigated, not because Defendants failed to
 disclose the investigations themselves. ¶¶44-45, 124, 236, 241, 260.

means that could be expected to continue.” DB 13, 15. To the contrary, the AC: (i) identifies Defendants’ specific statements regarding the IRC’s efforts to “help” patients obtain insurance coverage for Subsys through “proper” business practices (¶¶167, 168, 184, 199, 208, 217, 228) and the measures taken by the Company to achieve and maintain legal compliance (¶¶204, 206, 218, 224); and (ii) explains why, having put each of these topics at issue, Defendants were obligated to disclose these concealed facts, including the particular misconduct underlying the Off-Label/Kickback Scheme and the IRC Fraud, the nondisclosure of which rendered those statements materially misleading (*supra* at III.A.2).

Third, ignoring the AC’s allegations, Defendants incorrectly contend that certain of their misrepresentations are not false because the statements do not implicate either off-label marketing or the IRC unit. *See* DB 10, 12-14. For example, Defendants assert that a statement concerning *Defendants’* interactions with insurance providers is not false because it does not specifically mention the IRC. DB 12-13 (citing ¶167). Plaintiff, however, alleges that this statement omitted the material fact that the IRC helped patients obtain “access” to Subsys by systematically lying to PBMs about patients’ diagnoses. ¶¶136-61, 255-71, 276-77, 285-90; *see, e.g., Apollo*, 395 F. Supp. 2d at 921-22. Defendants also contend that their claimed commitment “to complying with laws” cannot be false because the AC does not allege facts demonstrating that these statements did not “accurately reflect corporate policy and the Company’s aspirations.” DB 14 (citing ¶¶204, 206). The AC, however, alleges that these statements were misleading when made in August 2015 because Insys was actively marketing Subsys for off-label uses, paying kickbacks to doctors, and defrauding PBMs. ¶¶159-63, 229. Thus, even if it were the Company’s policy to comply with the law, Insys was clearly violating it at the time Defendants made these statements. *Gilead*, 2009 WL 1561584, at *3.¹⁰

¹⁰ The distinction that Defendants attempt to draw between Insys’ efforts “to ensure that insurance plans covered Subsys in the first place” versus the IRC’s efforts “to ensure that [the PBMs] granted prior authorizations” (DB 13) is meaningless. Under

B. The AC Sufficiently Alleges Scienter

Facts raising a strong inference that Defendants were at least deliberately reckless “as to the possibility of misleading investors” allege scienter. *Berson*, 527 F.3d at 987. A defendant is deliberately reckless “if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort.” *Reese*, 747 F.3d at 569. Pleading that defendants had actual knowledge of the fraud is not required. *See S. Ferry LP #2 v. Killinger*, 687 F. Supp. 2d 1248, 1257 (W.D. Wash. 2009) (sufficient allegations “identify the problem that the individual defendants ought to have known about—not that they, in fact, know about it”).

In evaluating scienter allegations, courts must consider the totality of circumstances, rather than scrutinize each scienter allegation separately. *See In re VeriFone Hldgs., Inc. Sec. Litig.*, 704 F.3d 694, 703 (9th Cir. 2012) (courts must avoid “undu[e] focus” on separate allegations “to the exclusion of the whole picture”). Scienter is sufficiently pled where the allegations, taken collectively, would lead a reasonable person to “deem the inference of scienter at least as strong as any opposing inference[.]” *Tellabs*, 551 U.S. at 324, 326 (inference “need not be irrefutable” or “most plausible”).

1. Insys, Babich, and Burlakoff’s Direct Knowledge

The AC’s detailed facts demonstrate Babich and Burlakoff’s direct knowledge of the Off-Label/Kickback Scheme. For example, Burlakoff instructed the sales force to increase off-label Subsys prescriptions by reviewing doctors’ files for new Subsys patients (irrespective of whether they had BTCP) and for current Subsys patients whose doses could be increased (irrespective of the effectiveness of the current dose). ¶106; *see Amgen* 544 F. Supp. 2d at 1020. Babich and Burlakoff also knew Insys’ “speakers program” was an illegal kickback scheme—*i.e.*, doctors were paid to write high-dose

either interpretation, Defendants’ failure to disclose the IRC Fraud rendered this statement materially misleading. *See, e.g., Amgen*, 544 F. Supp. 2d at 1034.

1 off-label Subsys prescriptions, and many of the paid “speakers” did not treat cancer
 2 patients and/or were not trained to prescribe TIRFs. ¶¶91-93, 123; *see Amgen*, 544 F.
 3 Supp. 2d at 1020. Babich and Burlakoff likewise knew that the sales force used an off-
 4 the-books credit card to ply doctors with in-kind kickbacks. ¶133.

5 As CEO and VP of Sales, respectively, Babich and Burlakoff’s direct knowledge
 6 of the Off-Label/Kickback Scheme is imputed to Insys. *See Hollinger v. Titan Capital*
 7 *Corp.*, 914 F.2d 1564, 1576-78 (9th Cir. 1990) (a corporation’s scienter is derived from
 8 its employees and agents); *In re Energy Recovery Inc. Sec. Litig.*, 2016 WL 324150, at
 9 *24 (N.D. Cal. Jan. 27, 2016) (collecting cases).¹¹ Likewise, other Insys executives’
 10 scienter can be imputed to the Company. *See Matrix Capital Mgmt. Fund. L.P. v.*
 11 *BearingPoint, Inc.*, 576 F.3d 172, 189-90 (4th Cir. 2009); *accord Kyung Cho v. UCBH*
 12 *Hldgs., Inc.*, 890 F. Supp. 2d 1190, 1204-05 (N.D. Cal. 2012) (imputing scienter of
 13 former vice president and unnamed individuals to company).

14 For example, the AC alleges that the Director of Sales, Rich Simon, and Subsys
 15 sales executive, Karen Hill, were responsible for ensuring that Insys obtained a “return
 16 on investment” from doctors paid kickbacks through the “speakers program” by, among
 17 other things, threatening to cease paying kickbacks if the doctors did not write more
 18 scripts. ¶¶116, 122-123. The AC also alleges that district and regional managers orally
 19 instructed sales representatives to disregard sales training and promote off-label, telling
 20 employees to “[d]o what you need to do” to “[j]ust sell” (¶99), and pressured them
 21 through automatic emails (which included “top management”) to persuade doctors to
 22 increase off-label Subsys doses when they prescribed initial doses of 100mcg or
 23

24 ¹¹ Defendants’ “group pleading” arguments rely on inapplicable cases where the
 25 plaintiff failed to allege scienter for any individual defendant. *See DB 16-17* (citing
 26 *Oregon Pub. Emps. Ret. Fund v. Apollo Grp., Inc.*, 774 F.3d 598, 607-08 (9th Cir.
 27 2014); *Glazer*, 549 F.3d at 745; *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1063
 28 (9th Cir. 2014)). Indeed, *Glazer* did not address the viability of collective scienter and,
 since *Glazer* was decided, many courts in this Circuit have imputed to companies the
 scienter of their employees. *See, e.g., In re Cadence Design Sys. Inc. Sec. Litig.*, 692 F.
 Supp. 2d 1181, 1192 n.8 (N.D. Cal. 2010); *Curry v. Hansen Med., Inc.*, 2012WL
 3242447, at * 13 (N.D. Cal. Aug. 10, 2012).

200mcg (¶104). *See Amgen*, 544 U.S. at 1020. Further, the AC contains particularized allegations demonstrating the direct knowledge of Elizabeth Gurrieri, the head of the IRC (and that of her supervisor, Michael Gurry, and her successor, Jeff Kabos), of the IRC Fraud, including the IRC’s use of “the spiel” and falsification of insurance codes. ¶¶141-42, 145-49, 151-57, 160-63.

2. The Importance of Subsys to Insys and Defendants’ Access to Information Raise a Strong Inference of Scienter

Scienter also is adequately pled through allegations that: (i) “the nature of the relevant fact is of such prominence that it would be absurd to suggest that management was without knowledge of the matter”; and/or (ii) “suggest [] defendants had actual access to the disputed information.” *Reese* 747 F.3d at 575, 576. Plaintiff sufficiently pleads both scenarios. *See S. Ferry*, 687 F. Supp. 2d at 1256-57.

The Importance of Subsys Sales to Insys. Subsys was the heart of Insys’ business, with the drug’s rapid revenue growth (*e.g.*, averaging 91% per quarter, year-over-year until 1Q16) responsible for *no less than 98% of Insys’ quarterly revenues* during the Class Period. ¶79; *see, e.g., Medtronic*, 2010 U.S. Dist. LEXIS 10029 at *7 (medical device generating 6% of total sales raises a plausible inference that senior management would have known about the product’s off-label marketing). Indeed, Defendants discussed Subsys prescriptions, 80% of which were off-label, “*every single day, because Subsys is so important to us.*” ¶¶2, 9, 57, 79, 256, 269-70; *Berson*, 527 F.3d at 988.¹² Further, given Subsys’ costs, the high number of off-label prescriptions, and strict formularies preventing PBMs from authorizing coverage for off-label prescriptions, the IRC’s approval rate (and the methods by which it was achieved) would have been important to and known by Defendants. ¶¶59, 76-77, 140, 276-77.

¹² Defendants baselessly suggest that they only began meeting every single day to discuss Subsys prescriptions after Kapoor replaced Babich as CEO in November 2015. DB 19. Not only is this nowhere alleged in the AC, but it also depends upon an implausible inference that the Company’s sole revenue-generating product only became “so important” three years after FDA approval.

As such, it would be absurd to suggest that Defendants were unaware of the Off-Label/Kickback Scheme and IRC Fraud. *See supra* at §II.B; *Berson*, 527 F.3d at 988; *Impax*, 36 F. Supp. 3d at 969 (“it is ‘absurd’ to think that the CEO and CFO of a pharmaceutical company would be unaware of the alleged substandard, non-compliant conditions pervading their company’s manufacturing and quality control divisions—the heart of a company”); *Flynn*, 2016 WL 3360676, *15 (executives presumed to know about problems with product generating all of company’s net sales); *Roberti v. OSI Sys., Inc.*, 2015 WL 1985562, at *13 (C.D. Cal. Feb. 27, 2015) (defendants charged with knowledge of “largest and most profitable division”); *accord Forest Labs.*, 2006 WL 5616712, at *10 (knowledge presumed drugs at issue were company’s core business).

Defendants’ Access to Information. The AC also alleges that the Individual Defendants, and therefore Insys, had actual access to information undermining their public statements. *See S. Ferry, LP #2 v. Killinger*, 542 F.3d 776, 786 (9th Cir. 2008). Significantly, Kapoor publicly admitted that he and others monitored Subsys prescription data *daily*. ¶¶256, 270, 278; *see Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1231 (9th Cir. 2004) (defendants’ admission that “[w]e know exactly how much we have sold in the last hour around the world” indicative of scienter).¹³ Each Defendant also had access to and relied upon daily sales numbers and market share information from the TIRF-REMS Access Program, which Defendants repeatedly referenced. ¶¶6, 69-70; *In re Daou Sys., Inc.*, 411 F.3d 1006, 1022-23 (9th Cir. 2005) (scienter alleged where defendants monitored data that was subject of misrepresentations); *Oracle*, 380 F.3d at 1231 (defendants’ monitoring of portions of a global database sufficient to infer knowledge of improprieties); *In re Countrywide Fin. Corp. Deriv. Litig.*, 554 F. Supp. 2d 1044, 1065 (C.D. Cal. 2008) (in “a highly regulated industry . . . the company, it can be inferred, constantly monitors reports.”). Given the

¹³ Kapoor’s admission, together with his understanding of FDA rules, further demonstrates his scienter. *See Reese*, 747 F.3d at 572 (“little room for misunderstanding on [defendant’s] part . . . given her role and responsibility”). Accordingly, Defendants’ contrary assertion (DB 22) must be rejected.

specificity of the information to which Defendants had access, the cases cited at DB 19 are factually inapposite. *See, e.g., In re Diamond Foods, Inc.*, 2012 WL 6000923, at *12 (N.D. Cal. Nov. 30, 2012).

Additionally, as VP of Sales, Burlakoff hired, trained, and motivated the sales force to promote Subsys off-label. ¶¶96, 99, 106, 133, 260, 263-64; *Countrywide*, 554 F. Supp. 2d at 1065 (compensation incentivizing employees to increase loan volume at the expense of generating quality loans supported scienter). Similarly, Burlakoff, Kapoor, and Babich participated in recruiting and supervising doctors under the “speakers program.” ¶¶91-93, 123; *see Amgen*, 544 F. Supp. 2d at 1020, 1029 (scienter established where defendants created a “speakers program”). Likewise, Babich and Baker certified Insys’ financial results, in which the Company reported that no less than 98% of its revenues were from sales of Subsys (at least 80% of which were off-label). *See* ¶¶169, 261-62; *Impax*, 36 F. Supp. 3d at 969. Thus, any suggestion that Defendants “innocently missed the most important details,” regarding the Off-Label/Kickback Scheme or the IRC Fraud is simply implausible. *See Cadence*, 692 F. Supp. 2d at 1191.¹⁴

Moreover, any “inference that [Defendants] did not have access to the [relevant] data is directly contradicted by the fact that [they] specifically addressed it in [their] statement[s].” *Reese*, 747 F.3d at 572. Here, as set forth in Section III.A.2, Defendants made detailed factual statements concerning Subsys revenues and third-party coverage of prescriptions (¶¶166-69, 176-77, 182-87, 193-94, 196-99, 206-08, 212-18), while misrepresenting and omitting the sources of those revenues (¶¶172-73, 179-80, 189-92, 195, 201-02, 209-10, 219-22). *See Reese*, 747 F.3d at 572; *OSI*, 2015 WL 1985562, at *12 (scienter adequately alleged where individual defendants made “detailed factual statement[s], contradicting important data to which [they] had access”). By repeatedly referencing the source of Subsys revenues and the Company’s interactions with PBMs,

¹⁴ Defendants do not explain how allegations regarding Burlakoff’s aggressive sales practices are “too attenuated” to show his knowledge of “widespread misconduct.” DB 29. As VP of Sales, Burlakoff must have known about all aspects of Insys’ nationwide promotion of Subsys. *See, e.g., Reese*, 747 F.3d at 572.

Defendants “bridge[] the [scienter] gap.” *Reese*, 747 F.3d at 572.¹⁵

3. Other Indicia of Scienter Support a Strong Inference

The AC alleges other indicia of scienter that also support a strong inference. *See In re Sunpower Sec. Litig.*, 2011 WL 7404238, at *4 (N.D. Cal. Dec. 19, 2011) (the “combined weight” of the allegations demonstrated scienter).

Executive Resignations. Under “highly suspicious” circumstances, executive resignations support a strong inference of scienter. *See Middlesex Ret. Sys. v. Quest Software, Inc.*, 2008 WL 7084629, at *8-9 (C.D. Cal. July 10, 2008); *In re UTStarcom, Inc. Sec. Litig.*, 617 F. Supp. 2d 964, 976 (N.D. Cal. 2009) (“the proximity of Defendants’ departures to the [] investigations adds one more piece to the scienter puzzle”). Here, the AC alleges that Babich’s “resignation” occurred shortly after one of the “speakers” (Alfonso), for whom Babich personally approved two years’ worth of kickbacks (tied, in part, to speaking events Babich’s wife attended), pled guilty to receiving those kickbacks. ¶¶241, 260.¹⁶ The AC also alleges that Kapoor fired Babich because he was “closest to the issues” under federal investigation. *Id.* Moreover, unlike most long-tenured executives’ resignations (Babich served as Insys’ CEO for 8 years), Babich’s November 5, 2015 resignation took effect the day before it was announced. ¶¶28, 214, 259. *See In re Adaptive Broadband Sec. Litig.*, 2002 WL 989478, at *14 (N.D. Cal. Apr. 2, 2002) (scienter alleged where immediate restructuring of important executive position coincided with disclosure of company’s improprieties); *In re Galena*

¹⁵ Defendants’ argument that the Court should not consider allegations based on purported hearsay (DB 20-22), overlooks that it is improper to “transpose to the pleading stage” evidentiary standards “used at the summary judgment and judgment-as-a-matter-of-law stages.” *Tellabs*, 551 U.S. at 324, n.5. Thus, when a “newspaper article includes numerous factual particulars and is based on an independent investigative effort, it is a source that may be credited” in analyzing scienter allegations. *In re McKesson HBOC, Inc. Sec. Litig.*, 126 F. Supp. 2d 1248, 1272 (N.D. Cal. 2000). Defendants’ cases are not to the contrary.

¹⁶ Defendants attempt to distinguish “budgeted payments” from “budgeted kickback payments” to argue that Babich’s approval of “a speaker program budget” was innocent. DB 23. But the AC alleges that the entire speakers program was an illegal kickback scheme. *See* ¶¶68, 71-73, 110-30. In any event, Babich knew that Insys expected a “return on [] investment” from illicit speaker kickbacks (¶123).

Biopharma, Inc. Sec. Litig., 117 F. Supp. 3d 1145, 1167 (D. Ore. 2015) (scienter alleged where CEO's resignation announced "after the conduct came to light"). Accordingly, Defendants' assertion that Babich's resignation was not "accompanied by suspicious circumstances" (DB 20) ignores the AC's plain allegations.

Government Investigations. Government investigations addressing the alleged misconduct can "bolster the inference of scienter." *Reese*, 747 F.3d at 575; *accord* DB 20 (citing *Thorpe v. Walter Inv. Mgmt., Corp.*, 111 F. Supp. 3d 1336, 1376 (S.D. Fla. 2015) (government investigations "can be seen as one more piece of the [scienter] puzzle"); *Washtenaw Cty. Emps. Ret. Sys. v. Avid Tech., Inc.*, 28 F. Supp. 3d 93, 115 (D. Mass. 2014) (collecting cases)). Here, Plaintiff alleges that prior to and during the Class Period, Insys was the subject of government investigations related to its Off-Label/Kickback Scheme. *See, e.g.*, ¶¶230, 232, 234, 236-37, 246, 252, 289-90. Defendants' cooperation in these regulatory investigations before and during the Class Period (*see, e.g.*, DX20 at 3) further supports an inference that they knew of the misconduct.¹⁷

4. Defendants Offer No Plausible Competing Inference

When viewed holistically, Plaintiff's inference of scienter is far more compelling. *Tellabs*, 551 U.S. at 326; *Reese*, 747 F.3d at 577 ("looking at the totality of the circumstances under the *Tellabs* analysis makes the [plaintiff's] inference irresistible"). In fact, *Defendants have not offered any plausible inference* that they did not know, or were not deliberately reckless in disregarding, that Subsys sales during the Class Period were the byproduct of the Off-Label/Kickback Scheme and IRC Fraud. *See Middlesex Ret. Sys. v. Quest Software Inc.*, 527 F. Supp. 2d 1164, 1188 (C.D. Cal. 2007) (allegations raised inference of scienter where defendants had "not offered any plausible

¹⁷ Contrary to Defendants' assertion (DB 20), Insys' retaliation against whistleblowers can support an inference of scienter. *See, e.g., In re Pfizer Inc. S'holder Deriv. Litig.*, 722 F. Supp. 2d 453, 456 (S.D.N.Y. 2010) (the company "kept careful track" of illegal activities demonstrated by its "retaliat[iation] against employees who reported internally that Pfizer's [off-label] marketing practices were illegal").

argument . . . to lean away from a finding of scienter”). Instead, Defendants’ inferences ignore the facts alleged in the AC. *See id.* at 1181 (“all reasonable inferences must be drawn from the allegations”).

For instance, Defendants argue that the “*only* plausible inference” from their denials of wrongdoing is that they were not aware of any contrary facts (DB 19), *but nothing* in the AC supports this inference. Rather, the AC alleges that Defendants conceived, implemented, and monitored the Off-Label/Kickback Scheme and IRC Fraud. ¶¶80-164. Further, as discussed *supra* at III.A.4, Defendants’ repeated denials clearly implicate their scienter—Defendants either concealed Insys’ illegal conduct with respect to Subsys or deliberately disregarded it. Likewise, Defendants’ assertion that Insys’ boilerplate warnings of its exposure to the potential risk of employee misconduct evidences a lack of intent to defraud (DB 17) ignores that Insys issued these generic warnings while Defendants *were engaged in* the Off-Label/Kickback Scheme and IRC Fraud. *See, e.g., Flynn*, 2016 WL 3360676, at *10 (disclosures that “speak[] about [] risks . . . in the abstract, with no indication that the risk[s] ‘may already have come to fruition,’ do not shield the speaker from liability); *In re Stratosphere Corp. Sec. Litig.*, 1 F. Supp. 2d 1096, 1118 (D. Nev. 1998) (when potential risks are ongoing, defendants “cannot insulate these statements with general language about the risks inherent in every [pharmaceutical] enterprise”).

C. The AC Adequately Pleads Loss Causation

Loss causation allegations must show “a causal connection between the material misrepresentation and the loss.” *Dura*, 544 U.S. at 342. Allegations demonstrating that the relevant truth was revealed “through ‘corrective disclosures’ which ‘caused the company’s stock price to drop and investors to lose money’” are sufficient. *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1209 (9th Cir. 2016). Loss causation also can be established under the “materialization of the risk” theory where “‘a misstatement or omission is the ‘proximate cause’ of an investment loss if the risk that caused the loss

1 was within the zone of risk concealed by the misrepresentations and omissions.”
 2 *Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1120
 3 (9th Cir. 2013).¹⁸

4 A plaintiff must provide “some indication of the loss and the causal connection
 5 that that the plaintiff has in mind.” *Dura*, 544 U.S. at 347. However, “loss causation is a
 6 ‘context-dependent’ inquiry . . . as there are an ‘infinite variety’ of ways for a tort to
 7 cause a loss.” *Lloyd*, 811 F.3d at 1210. Thus, “[d]isclosure of the fraud is not a *sine qua*
 8 *non* of loss causation, which may be shown even where the alleged fraud is not
 9 necessarily revealed prior to the economic loss.” *Nuveen*, 730 F.3d at 1120. Loss
 10 causation is established if the disclosures are a substantial factor in causing the price
 11 declines. *See, e.g., Daou*, 411 F.3d at 1026.

12 The AC alleges nine partial corrective disclosures and/or materializations of
 13 foreseeable risks (each herein a “Disclosure”) concealed by Defendants’ misconduct.
 14 *See* ¶¶231-36, 238-45, 247-51, 302-46; *Daou*, 411 F.3d at 1026 (loss causation pled
 15 through partial disclosures); *Mauss v. NuVasive, Inc.*, 2016 WL 3681831, at *12 (S.D.
 16 Cal. July 12, 2016) (partial disclosures spanning 20 months allege loss causation). For
 17 each Disclosure, the AC: (i) identifies the new information that undermined Defendants’
 18 prior statements; (ii) connects this new information to the Off-Label/Kickback Scheme
 19 and/or IRC Fraud; and (iii) alleges the foreseeable negative impact that the new
 20 information had upon Insys’ stock price. ¶¶231-36, 238-45, 247-51, 302-46.

21 For example, the AC connects price declines after the Disclosures on November
 22 27, 2014 (8.58% decline), April 24, 2015 (9.61% decline), May 20, 2015 (4.43%

23 ¹⁸ Courts within this Circuit have more than “experimented” with the
 24 materialization of the risk theory (DB 28). *See, e.g., In re Amgen Sec. Litig.*, 2014 U.S.
 25 Dist LEXIS 183034, at *70 (C.D. Cal. Aug. 4, 2014) (collecting cases). Further, a
 26 “decisive majority of circuits” have adopted the materialization of the risk theory of loss
 27 causation. *OPERS v. Federal Home Mortgage Corp.*, 2016 WL 3916011, at *6 (6th Cir.
 28 Jul. 20, 2016). Perceiving inconsistency in the Ninth Circuit’s post-*Dura* decisions,
 Judge Campbell certified the question of the appropriate test for loss causation under 28
 U.S.C. §1292(b). *See Smilovits v. First Solar, Inc.*, 119 F. Supp. 3d 978, 992-93 (D.
 Ariz. 2015). That appeal is pending with the Ninth Circuit, No. 15-17282.

decline), and June 23 & 25, 2015 (12.64% decline) to Defendants' misconduct. ¶¶304-06, 308-10, 312-14. On each of these days, investors learned new information regarding the Off-Label/Kickback Scheme (e.g., specific amounts of kickbacks Insys paid doctors based on information from "a new federal database," revealed on November 27, 2014) and the consequences thereof, including the arrests of Drs. Ruan and Couch for prescribing fentanyl "not for a legitimate medical purpose" (May 20, 2015 Disclosure), and Alfonso's guilty plea to receiving approximately \$83,000 in kickbacks from Insys (June 23 & 25, 2015 Disclosures). ¶¶231-36, 304-19; DX21-23, 25, 26. These events revealed the findings and expanding scope of the government's investigation of Insys' practices (the April 24, 2015 Disclosure) and served as "a strong indication" to the market "that prosecutors [were] moving aggressively in their investigation." ¶¶232-33, 236, 308-09, 316-17; *see In re Montage Tech. Grp. Ltd. Sec. Litig.*, 78 F. Supp. 3d 1215, 1227 (N.D. Cal. 2015).¹⁹

The AC also connects the price declines after the Disclosures on November 4, 2015 (8.5% decline), November 5, 2015 (3.60% decline), December 3, 2015 (18.54% decline), and January 25, 2016 (4.74% decline) to Defendants' misconduct by alleging that these Disclosures revealed new information regarding Insys' Off-Label/Kickback Scheme and the IRC Fraud. Specifically, the November 4, 2015 Disclosure revealed that the DHHS had identified Subsys as a source of a form of medical fraud (known as "diversion") that includes prescribing drugs for unintended uses. *See* ¶¶238, 320; DX28; *Amgen*, 544 F. Supp. 2d at 1026 (loss causation alleged where disclosure was FDA expression of concern regarding reports of off-label marketing). The November 5, 2015 and December 3, 2015 Disclosures revealed Defendant Babich's unexpected and

¹⁹ Defendants' apparent assertion that Plaintiff cannot represent investors who sustained losses causally linked to the April 24, 2015 and May 20, 2015 Disclosures because Plaintiff's purchases of Insys common stock took place thereafter (DB 25) provides no basis for dismissing any of the alleged claims. *See, e.g., In re Connectics Corp. Sec. Litig.*, 257 F.R.D. 572, 576-77 (N.D. Cal. 2009) (proposed class representative who purchased stock after partial corrective disclosure could represent class as defined) (collecting cases).

1 immediate “resignation” from Insys due to his proximity “to the issues” under federal
 2 investigation (*i.e.*, Subsys off-label marketing and kickbacks) and his approval of two
 3 years’ worth of budgeted kickback payments to Alfonso (who hosted 70 speaker events,
 4 many of which were attended by Babich’s wife, an Insys sales representative). *See*
 5 ¶¶240-43, 324-26, 328-30; DX31; *Mauss*, 2016 WL 3681831, at *10 (resignation of
 6 CEO and accompanying stock price decline qualified as corrective disclosure). With
 7 respect to the IRC Fraud, the AC alleges the December 3, 2015 and January 25, 2016
 8 Disclosures revealed the bonus compensation IRC employees received for defrauding
 9 PBMs, and the Company’s evolving IRC Fraud strategy from the second half of 2014
 10 through the fall of 2015 based on first-hand accounts, Insys documents, and audio
 11 recordings of IRC meetings. *See* ¶¶241-43, 245, 328-30, 332-35; DX31-32.

12 Finally, the AC connects the 19.37% price decline on April 11, 2016 to
 13 Defendants’ misconduct by alleging that Insys’ disclosure that Subsys 1Q16 net
 14 revenues would be significantly lower than expected—\$61 million to \$62 million
 15 instead of \$86 million for the same period—revealed that Defendants had presented “a
 16 picture of Subsys that ***did not entirely square with reality***” during the Class Period.
 17 ¶¶247-51, 337-38. The lower Subsys revenues resulted from a decline in new
 18 prescriptions due to “price and payer considerations,” including the IRC Fraud, with
 19 “fewer patients . . . initiating therapy.” ¶¶162, 164, 247-51; *see In re Gilead Sec. Litig.*,
 20 536 F.3d 1049, 1058 (9th Cir. 2008) (disclosure of “less-than-expected revenues”
 21 connected to waning demand due to disclosure of off-label marketing scheme).

22 In response, Defendants make several unavailing arguments. *First*, Defendants
 23 incorrectly contend that none of the Disclosures revealed either “new news” or
 24 previously concealed risks. DB 24-28. This argument ignores Defendants’ consistent
 25 (and false) denials of their Class Period misconduct. *See, e.g.*, ¶¶168, 193-94, 213, 224,
 26 228; *Gilead*, 536 F.3d at 1058 (certain corrective events insufficient by themselves to
 27 undermine company’s positive statements); *In re Amgen Inc. Sec. Litig.*, 2014 U.S. Dist.
 28

LEXIS 183034, at *50 (rejecting “truth-on-the-market” causation defense where withheld information was not provided to investors “with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression” provided by defendants). Defendants also fail to account for the steep declines in the price of Insys stock in response to each of the Disclosures, including nearly 20% drops on December 3, 2015 and April 11, 2016. ¶¶231, 233, 235-36, 239-40, 242, 245, 247; *Asher v. Baxter, Int’l Inc.*, 377 F.3d 727, 734 (7th Cir. 2004) (if no Disclosure contained new news, then “it is hard to understand the sharp drop in the price of [Insys’] stock” in response to each).²⁰

Second, Defendants’ assertion that the announcement of an investigation, standing alone, cannot support loss causation (DB 25-26), ignores the law and the AC’s allegations. Disclosures of investigations *are* sufficient to allege loss causation where, as alleged here, subsequent disclosures reveal the expanding scope and/or findings of misconduct. *See* ¶¶232, 234-36; *Lloyd*, 811 F.3d at 1210; *Mauss*, 2016 WL 3681831, at *9. Significantly, in addition to the Disclosures discussed above, the AC alleges that: (i) Insys settled the ODOJ’s claims regarding its Subsys marketing on August 5, 2015 (¶237); (ii) former Subsys sales representative Perhacs pled guilty on February 17, 2016 to illegally paying Drs. Ruan and Couch kickbacks (¶246); and (iii) two former New York sales representatives were indicted for illegally paying kickbacks to doctors (¶252). Each of these events affirms the causal connection between the Disclosures and the alleged fraud. *See Lloyd*, 811 F.3d at 1210.

Third, Defendants incorrectly assert that facts about the IRC Fraud revealed for the first time in the December 3, 2015 and January 25, 2016 *SIRF* articles were “recycled” from the Prior Securities Complaints (“PSC”) and therefore already known.

²⁰ Defendants’ suggestion that the temporary recovery in Insys’ stock price negates any inference that Babich’s resignation caused investors’ losses is based “on dicta from *Metzler*, and [] basic economic principles preclude dismissing a complaint on these grounds.” *Nathanson v. Polycom*, 87 F. Supp. 3d 966, 985 (N.D. Cal. 2015); *see also Acticon AG v. China N.E. Petroleum Hldgs., Ltd.*, 692 F.3d 34, 26 (2d Cir. 2012) (price recovery does not negate inference that plaintiff suffered losses).

1 *See* DB 27. Both of these Disclosures, however, revealed new information concerning
 2 the IRC Fraud that *did not exist at the time the PSC was filed*. Indeed, these
 3 Disclosures addressed facts in 2015, more than a year after the end of the Class Period
 4 alleged in the PSC and nearly 2.5 years after the witness to whom the handful of IRC
 5 allegations in the PSC were attributed had left the Company. *See* Doc. 41 in 14-cv-
 6 01043-GMS (D. Ariz.) at ¶¶184-96. The only plausible inference is that the facts
 7 revealed on December 3, 2015 and January 25, 2016 were new. *See, e.g., Amgen*, 2014
 8 U.S. Dist. LEXIS 183034, at *49.

9 *Finally*, Defendants’ premature factual challenges are improper. *See Gilead*, 536
 10 F. 3d at 1057 (loss causation is a matter of proof at trial). Defendants’ suggestion that
 11 the November 27, 2014 Disclosure did not address a Company-wide practice (DB 25)
 12 ignores the wide geographic dispersion of the misconduct revealed therein. *See*, ¶¶115,
 13 231; DX21. Likewise, Defendants’ assertion that the May 20, 2015 Disclosure of Ruan
 14 and Couch’s arrests is not corrective because it did not mention Insys or Subsys (DB
 15 25), ignores that the arrests were for improper fentanyl prescriptions and that investors
 16 already knew Drs. Ruan and Couch were the largest Subsys prescribers. *See* ¶¶42-43,
 17 233; DX22 at 9. Defendants’ contentions that the December 3, 2015 Disclosure is
 18 “unreliable” (DB 27) and the April 11, 2016 price decline was due to lower revenues
 19 alone also seek the improper resolution of factual issues. *See Gilead*, 536 F.3d at 1054,
 20 1057-58 (loss causation adequately alleged through decline in sales caused by increased
 21 scrutiny of off-label marketing).²¹

22 **IV. CONCLUSION**

23 For the reasons stated herein, Defendants’ Motion should be denied. If the Court
 24 determines that any of the AC’s allegations are deficient, Plaintiff respectfully requests
 25 leave to amend.

27 ²¹ Because the AC pleads a primary violation of §10(b), Defendants’ argument
 28 against §20(a) liability (DB 28) fails. *See In re LDK Solar Sec. Litig.*, 584 F. Supp. 2d
 1230, 1252 (N.D. Cal. 2008).

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I hereby certify that on September 6, 2016, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing those persons who are CM/ECF registrants:

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